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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,171	07/01/2003	Carol A. Tosaya	D-02017A	5208

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EXAMINER
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KISH, JAMES M

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 09/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/612,171

Applicant(s)

TOSAYA ET AL.

Examiner

James Kish

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-96 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27, 30-43, 50-53, 56-66, 69, 71-79, 82-86 and 88-96 is/are rejected.
- 7) ☒ Claim(s) 28, 29, 44-49, 54, 55, 67, 68, 70, 80, 81 and 87 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____.  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/16/03</u> .   | 6) <input type="checkbox"/> Other: ____.                                    |

**DETAILED ACTION*****Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-96 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 6-17, and 20-99 of U.S. Patent Application No. 2005/0020945. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions disclose opening of a blood brain barrier to allow transference of compounds, whether it be CSF or a treatment agent, through the barrier using a similar, if not identical, apparatus.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-6, 11-16, 21-27, 30-36, 39-42, 49-56, 58, 60, 62-66, 69, 71-76, 78-79, 81-86, 88-90 and 92-96 are rejected under 35 U.S.C. 102(b) as being anticipated by Jolesz et al. (US Patent No. 5,752,515). Jolesz discloses a method and apparatus for treating neurological disorders by ultrasonic delivery of compounds through the blood-brain barrier (BBB). See column 3, lines 44-67. The ultrasound is applied through the skull itself via a phased array of transducers, a focused ultrasound transducer or a combination of ultrasound source and an acoustic lens, placed outside the skull (column 2, line 66 through column 3, line 37). The ultrasound can be focused electronically or mechanically (column 5, lines 33-41). Discussion of cavitation can be found throughout the reference, and particularly at column 5, line 64 through column 6, line 27. The invention allows for both continuous wave or burst (pulsed) mode operation (column 6, line 24). The device uses image-based localization of the region. Such images can be obtained on the devices described at column 6, lines 38-61. The effects of the skull bone are incorporated to allow the ultrasound to focus at a common location (column 7, lines 33-51).

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 7-10, 17-20, 41, 43, 59, 61, 77, 88 and 91 are rejected under 35 U.S.C. 102(e) as being anticipated by Briskin et al. (US Patent No. 6,464,680). Briskin discloses a method of enhancing cellular absorption of a substance delivered into a target region with the use of vibrational energy to the target region (see Abstract). The invention can be used in treatment of abnormalities of the brain (column 12, lines 4-14) by allowing treatment to brain cells protected by the blood-brain barrier (column 1, lines 54-55). In one embodiment, an injection needle and the ultrasound energy emitter are located on the end of a catheter and can be introduced through a blood vessel or other luminal cavity (column 3, lines 4-28). The ultrasound conditions induce a preferred cellular response that increases porosity and subsequent uptake of therapeutic agents (column 5, line 55 through column 6, line 8). See column 7, lines 43-55 for possible effects of drugs. The wave may be divergent or focused on a small spot with the resolution of the ultrasonic emitter device (column 9, lines 65-67 and column 11, lines 54-63). Column 5, lines 38-54 discuss the thermal index of the vasculature immediately around the device. It is monitored based on the equation found at line 43.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 37-38, 57 and 92 rejected under 35 U.S.C. 103(a) as being unpatentable over Jolesz et al in view of Hynynen et al (US Patent No. 6,514,221). Jolesz discloses a method and apparatus for treating neurological disorders by ultrasonic delivery of compounds through the blood-brain barrier (BBB). However, while cavitation is discussed by Jolesz, the compounds delivered through the BBB are not explicitly cavitation aiding agents. Hynynen teaches a method of opening the blood-organ barrier of a subject providing an exogenous agent (see Abstract). The agent is described as having microbubbles or solid particles contained within that will vaporize via body heat or ultrasonic energy (see all of column 5, as well as column 6, lines 1-43). There is also a measure of the temperature elevation due to the sonication (column 9, line 65 through column 10, line 12). Hynynen also discusses non-focused ultrasound at column 10, lines 36-57. It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate a cavitation inducing contrast agent as taught by Hynynen into the system of Jolesz in order to allow opening of the BBB at low enough energy levels so as not to induce thermal damage (see Abstract).

***Allowable Subject Matter***

5. Claims 28-29, 44-49, 54-55, 67-68, 70, 80-81 and 87 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Kish whose telephone number is 571-272-5554. The examiner can normally be reached on 8:30 - 5:00 ~ Mon. - Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JMK

  
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